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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,069	12/07/2006	Hidemitsu Kurihara	0230-0245PUS1	2459
2292 7590 08/04/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
BORGHEST, CHRISTINA M				
ART UNIT		PAPER NUMBER		
1649				
NOTIFICATION DATE		DELIVERY MODE		
08/04/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/571,069	Applicant(s) KURIHARA ET AL.
Examiner Christina Borgeest	Art Unit 1649

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 July 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 10-13, 15, 16 and 30.
Claim(s) withdrawn from consideration: 1-9 and 18-29.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☒ Other: See Continuation Sheet.

/Bridget E Bunner/
Primary Examiner, Art Unit 1647

Continuation of 3. NOTE: A new search has to be conducted for the new limitation of claim 10 (limited to hyaluronic acid).

Continuation of 13. Other: Applicants argue:

1) The Examiner employs hindsight reasoning and/or speculation as the Examiner is apparently attributing the occurrence of ankylosis solely to the absorbent material.

This argument has been considered but is not persuasive, because it is not an accurate characterization of the Examiner's comments. In the Final Rejection, the Examiner was responding to Applicants' arguments filed 24 November 2009 at p. 4 that when a PLGA carrier was used, periodontal tissue regeneration was not observed. The Examiner must consider and respond to all of Applicants arguments, and it was Applicants and not the Examiner who raised the issue about the PLGA implant in their Remarks filed 24 November 2009. The Examiner is not engaging in hindsight reasoning merely because she is responding to issues raised by Applicants.

2) Applicants argue that Wikesjo reflects the knowledge of one of skill in the art and that the occurrence of ankylosis strongly suggests that a therapy using the claimed product would not be efficacious.

This argument has been fully considered but is not found persuasive. The Examiner does not take issue with the assertion that ankylosis is a common side effect of GTR and she addresses this at p. 7, last paragraph through p. 8 of the Final Rejection mailed 5 April 2010, and the comments therein are hereby incorporated. However, as noted therein Wikesjo also teach bone regeneration encompassing 70% of defect height as well as new cementum, thus the Examiner is not of the opinion that based upon this one would conclude the claimed product was not efficacious.

3) Applicants submit that the Examiner has improperly dismissed all of the statements of Dr. Kurihara and that she is required to consider all rebuttal evidence.

This argument has been fully considered but is not found persuasive. First, the Examiner re-read the 17 page Final Rejection and noted that in fact, she did consider all of Dr. Kurihara's statements, though it was noted that evidence is given greater weight than argument.

It is noted at page 8 of the Response, Applicant reviews the statements from an alleged second Kurihara declaration submitted under 37 CFR 1.132. Although Applicant points out at the bottom of page 9 of the response of 06 July 2010 that a declaration was filed with the response of August 24, 2009, no such response was filed in the instant application on that date. After extensive review of the prosecution history, the Examiner has determined that only one Kurihara declaration under 37 CFR 1.132 has been filed (24 November 2009). The Examiner is unable to address Applicant's comments on page 8 of the Response since the second Kurihara declaration was not filed in the instant application and hence, could not be independently evaluated.